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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,010	01/11/2006	Richard Anthony Borman	620-410	8896

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EXAMINER	
RAO, SAVITHA M	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,010	BORMAN ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *92-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

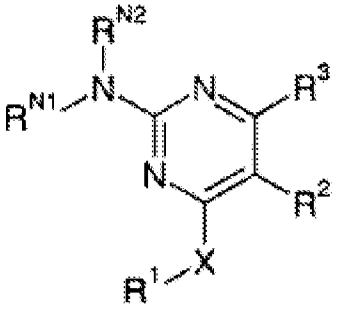
Claims 92-111 are currently pending in the instant application and are subject to a lack of unity requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

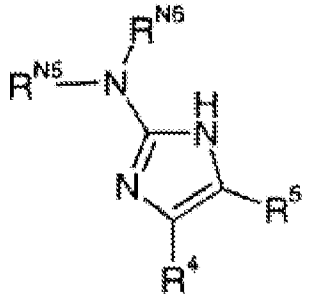
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I: Claims 92-95 are drawn to a pyrimidine compounds of formula (I) shown below, **Further election of species requirement 1 as set forth below is required upon electing this invention.**



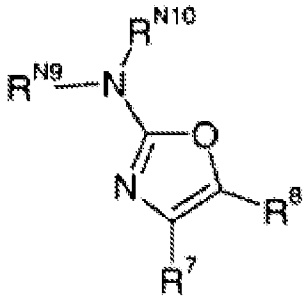
(I)

II. Group II: Claims 96-99 are drawn to imidazoles compounds of formula (II) shown below. **Further election of species requirement 2 as set forth below is required upon electing this invention.**

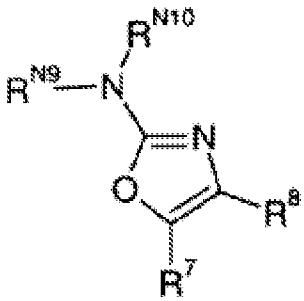


(II)

III. Group III: Claims 100-103 are drawn to oxazole compounds of formula (IIIa and IIIb) shown below. **Further election of species requirement 3 as set forth below is required upon electing this invention**

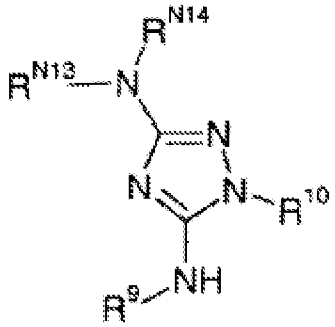


(IIIa)

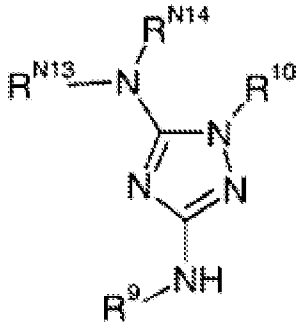


(IIIb)

IV. Group IV: Claims 104-107 are drawn to triazole compounds of formula (IVa and IVb) shown below. **Further election of species requirement 4 as set forth below is required upon electing this invention**.



(IVa)



(IVb)

V. Group V: Claims 108 is drawn to a method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of compounds of **Group I** above comprising compounds of formula (I). **Further election of species requirement 1 as set forth below is required upon electing this invention.**

VI. Group VI: Claims 109 is drawn to a method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group II** above comprising compounds of formula (II) **Further election of species requirement 2 as set forth below is required upon electing this invention**

VII. Group VII: Claims 110 is drawn to a method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group III** above comprising compounds of formula (IIIa or IIIb) **Further election of species requirement 3 as set forth below is required upon electing this invention.**

VIII. Group VIII: Claims 111 is drawn to a method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group IV** above comprising compounds of formula (IVa or IVb)

Further election of species requirement 4 as set forth below is required upon electing this invention

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a).

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Groups I -VIII lack unity of invention under 37 CFR 1.475 since the five groups (I-VIII) are not unified by the same or corresponding special feature as detailed below.

The special technical feature in **Group I** are **pyrimidine** compounds of formula (I) shown above.

The special technical feature in **Group II** are **imidazole** compounds of formula (II) shown above.

The special technical feature in **Group III** are **oxazole** compound of formula (IIIa and IIIb) shown above.

The special technical feature in **Group IV** are **triazole** compounds of formula (IVa and IVb) shown above.

The special technical feature in **Group V** is the method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group I** which involves identifying conditions which can be alleviated by 5-HT_{2B} receptor antagonism, Identifying patient population, determining routes of administration, preparing pharmaceutical compositions of the compounds with appropriate excepients, determining dosage requirements, administering the compositions, evaluating the prognosis of the condition.

The special technical feature in **Group VI** is the method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group II** which involves identifying conditions which can be alleviated by 5-HT_{2B} receptor antagonism, Identifying patient population, determining routes of administration, preparing pharmaceutical compositions of the compounds with

appropriate excepients, determining dosage requirements, administering the compositions, evaluating the prognosis of the condition

The special technical feature in **Group VII** is the method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group III** which involves identifying conditions which can be alleviated by 5-HT_{2B} receptor antagonism, Identifying patient population, determining routes of administration, preparing pharmaceutical compositions of the compounds with appropriate excepients, determining dosage requirements, administering the compositions, evaluating the prognosis of the condition

The special technical feature in **Group VIII** is the method of treating a condition which can be alleviated by antagonism of a 5-HT_{2B} receptor, which method comprises administering to a patient in need of treatment an effective amount of a compounds of **Group IV** which involves identifying conditions which can be alleviated by 5-HT_{2B} receptor antagonism, Identifying patient population, determining routes of administration, preparing pharmaceutical compositions of the compounds with appropriate excepients, determining dosage requirements, administering the compositions, evaluating the prognosis of the condition

Accordingly there is no same or corresponding special technical features unifying Groups I -VIII and thereby they lack unity.

For Groups I –VIII even if unity of invention under 37 CFR 1.475(a) is not considered lacking,(which in the instant case examiner believes to be lacking as they

are not unified by a special technical feature), under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of said product, and a use of said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of said product, and an apparatus or means specifically designed for carrying out the said process.

And according to 37 CFR 1.475(c): if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since in the instant application the claims are drawn to distinct inventions, based on, products and methods of using the products as shown above, and according to 37 CFR 1.475(e): the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claims.

The groups I-VIII therefore, lacks unity of invention.

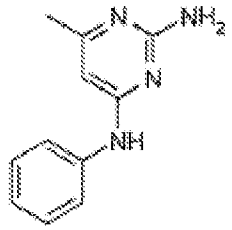
Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1. Election of specie requirement 1

If electing either Group I or Group V applicant is required to elect a single discloses specie from those claimed in instant claim 92 where in all the variables in the formula (I) are defined (for e.g. where X is NH , R^2 and R^3 are H, R^1 is phenyl etc), an example of a single disclosed specie is compound 2A disclosed in the specification page 57 as shown below;

N^4-phenyl-6-methyl-pyrimidine-2,4-diamine hydrochloric acid (2A)

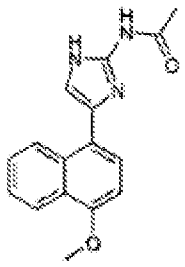


2. Election of specie requirement 2

If electing either Group II or Group VI applicant is required to elect a single discloses specie from those claimed in instant claim 96 where in all the variables in the formula (II) are defined (for e.g. where R^5 is H and R^{N5} is C=O

and R^{N6} is CH_3 etc), an example of a single disclosed specie is compound 103B disclosed in the specification page 91 as shown below;

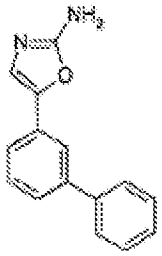
N-[4-(4-Methoxy-naphthalen-1-yl)-1H-imidazol-2-yl]-acetamide (103B):



3. Election of specie requirement 3

If electing either Group III or Group VII applicant is required to elect a single discloses specie from those claimed in instant claim 100 where in all the variables in the formula (IIIa or IIIb)) are defined (for e.g. where R^8 is H and R^{N9} and R^{N10} are H etc), an example of a single disclosed specie is compound 209A disclosed in the specification page 112 as shown below;

5-Biphenyl-3-yl-oxazol-2-ylamine (209A)

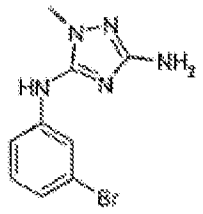


4. Election of specie requirement 4

If electing either Group IV or Group VIII applicant is required to elect a single discloses specie from those claimed in instant claim 104 where in all the

variables in the formula (IVa or IVb)) are defined (for e.g. where R^8 is H and R^{N9} and R^{N10} are H etc), an example of a single disclosed specie is compound 404 disclosed in the specification page 133 as shown below;

N^5-(3-bromo-phenyl)-1-methyl-1H-[1,2,4]triazole-3,5-diamine (404)



The species are structurally divergent, differ in their physical, chemical and biological properties and activities and thereby require searching in different class/subclasses and use of different search queries. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be

traversed (37 CFR 1.143) and (ii)identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be

fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 8 am to 5 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614